

6836-38

3/10/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAR 10 2014

Joanna Holcombe
Sr. Regulatory Services Associate
Lonza Inc.
90 Boroline RD
Allendale, NJ 07401

SUBJECT: Lonza BIO-Gentle
EPA Registration Number: 6836-38
Application Dated: February 4, 2014
Receipt Date: February 6, 2014

Dear Ms. Holcombe:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

- Addition of Spanish statement and minor labeling changes.

General Comments

Based on a review of the submitted information, this notification is acceptable. Your proposed changes will be made part of the record for this file.

Should you have any questions concerning this letter, please contact John Cowden at (703) 347-0259 or Velma Noble at (703) 308-6233.

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble".

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

 Environmental Protection Agency Washington, DC 20460	United States <input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 6836-38	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lonza Bio-Gentle	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Lonza Inc. 90 Boroline Road Allendale, NJ 07401	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Not Subject to PRIA

Label Notification to make minor changes to the label. Please see cover letter for details.

This notification is consistent with the provisions of PR-Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: Joanna Holcombe Date: 3/5/14

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input checked="" type="checkbox"/> Other (Specify) bag-in-box	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container Various (commercial & industrial only)		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Joanna Holcombe	Title Sr. Regulatory Services Associate	Telephone No. (Include Area Code) 678-627-2336
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <u>Joanna Holcombe</u>		
3. Title Sr. Regulatory Services Associate		
4. Typed Name Joanna Holcombe		5. Date <u>3/5/14</u>

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Via FedEx

Lonza Inc.
90 Boroline Road
Allendale, NJ 07401, USA

Ms. Velma Noble, PM-31
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2227 S. Crystal Drive
Arlington, VA 22202

Joanna Holcombe
Specialty Ingredients
Regulatory Assurance

Tel 678-627-2336
Fax 678-627-2081
joanna.holcombe@lonza.com

March 5, 2014

**SUBJECT: Lonza Bio-Gentle, EPA Reg. No. 6836-38
Application for Label Notification**

Dear Ms. Noble:

Lonza is submitting an application to make minor changes to the abovementioned product label.

Page 1:	Added new note to reviewer about the use of brackets and braces throughout the label. Designated the Spanish signal word as optional. Added placeholder for non-FIFRA
Page 3:	Replaced Spanish text and translation with the following: <i>{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}</i> <i>Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.</i> <i>[If you do not understand the label, find someone to explain it to you in detail.]</i>

Please find the enclosed documents in support of this notification:

- Application for Notification;
- Certification with Respect to Label Integrity;
- CD with label; and
- One copy of the proposed label with changes highlighted.

If you have any questions or need any additional information, please feel free to contact me at 678-627-2336.

Sincerely,
Lonza Inc.

Joanna Holcombe
Sr. Regulatory Services Associate

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Note to Reviewer:
[Language in brackets [AAA] is optional or interchangeable]
{Language in braces {AAA} is for informational purposes and will not appear on the final label}

LONZA BIO-GENTLE

BACTERIOSTATIC LAUNDRY SOFTENER CONCENTRATE WITH RESIDUAL BACTERIOSTATIC ACTIVITY

COMMERCIAL AND INDUSTRIAL USE ONLY

Active Ingredients:

Octyl Decyl Dimethyl Ammonium Chloride	15.0%
Diocetyl Dimethyl Ammonium Chloride.....	6.0%
Didecyl Dimethyl Ammonium Chloride.....	9.0%
Other Ingredients:	70.0%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See [right] [left] [side] [back] panel for Precautionary Statements and First Aid.

CAS. NO. MIXTURE

EPA Reg. No. 6836-38
EPA Est. No. (insert EPA Establishment No. here)
Net Weight (insert size of container here)

[DOT Symbols]
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

Manufactured by:
LONZA INC., 90 Boroline Road, Allendale, NJ 07401

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Wear goggles or face shield, protective clothing, and protective gloves (rubber, chemical resistant) when handling. May be fatal if absorbed through skin or swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15– 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

DO NOT USE OR STORE NEAR HEAT OR FLAME!

FOR HELP IN A CHEMICAL EMERGENCY CALL CHEMTREC 800-424-9300. BEFORE USING CONSULT MATERIAL SAFETY DATA SHEET.

*{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]*

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Use 1.00 fluid oz. [2 tablespoons] **LONZA BIO-GENTLE** per 100 lbs. of fabric [dry weight]. Use a maximum of 60 gallons [500 lbs.] of water per 100 lbs. of fabric [dry weight].

To soften laundered fabrics and obtain residual bacteriostatic activity against gram negative and / or gram positive odor-causing bacteria, dilute the appropriate amount of **LONZA BIO-GENTLE** in one to two gallons of water and then add to the wash-wheel at the beginning of the final rinse cycle.

Repeat the treatment of fabric with **LONZA BIO-GENTLE** after each washing.

{Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.

PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

{Note to reviewer: This Container Statement will be used only for containers 5 gallons or less:}

CONTAINER DISPOSAL:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

[Plastic and Metal Containers:] Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[For metal containers only: DO NOT cut or weld metal containers.]

[For Bag in Box Containers:] Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

{Note to reviewer: This Container Statement will be used for containers over 5 gallons:}

CONTAINER DISPOSAL:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

[Plastic and Metal Containers:] Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

[For metal containers only: DO NOT cut or weld metal containers.]

[Bag in Box Containers:] Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.